SETTLEMENT AGREEMENT BETWEEN MISSOURI BOARD OF PHARMACY AND PHARMAX PHARMACY

Comes now Pharmax Pharmacy ("Licensee or permit holder") and the Missouri Board of Pharmacy ("Board") and enter into this settlement agreement for the purpose of resolving the question of whether Licensee's pharmacy permit will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo 2000, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("AHC") regarding cause to discipline the Licensee's license, and, additionally, the right to a disciplinary hearing before the Board under § 621.110, RSMo 2000.

The Permit Holder acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against him; the right to present evidence on its own behalf at the hearing; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against him and, subsequently, the right to a disciplinary hearing before the Board at which time the Permit Holder may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against Licensee's permit. Being aware of these rights

provided to Permit Holder by operation of law, the Permit Holder knowingly and voluntarily waives each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to the Permit Holder.

The Permit Holder acknowledges that it has received a copy of the investigative report and other documents relied upon by the Board in determining there was cause to discipline Licensee's permit, along with citations to the law and/or regulations the Board believes was violated.

For the purpose of settling this dispute, Licensee stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Licensee's permit to operate a pharmacy in the state of Missouri, numbered 4781 is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621, as amended and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS AND CONCLUSIONS OF LAW

- 1. The Missouri Board of Pharmacy ("Board") is an agency of the State of Missouri created and established pursuant to § 338.110, RSMo 2000, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
- 2. Pharmax Pharmacy ("the Pharmacy or Licensee") is located at 673 W. Karsh, Farmington, Missouri.
- 3. The Pharmacy is licensed by the Board, Permit Number 4781. The Pharmacy's permit is and was current and active at all times relevant herein.

4. The Pharmacy is owned by David Holman and he serves as the permit holder for the Pharmacy.

5. An audit of the Pharmacy was conducted on August 19, 2009 by Board Inspectors Kidd and Wood. The audit revealed significant losses of controlled substances in the following particulars:

Drug	Milligram	No. of Tablets Missing
Hydrocodone/APAP	10/325	-1843
Hydrocodone/APAP	5/325	-482
Lorcet	10/650	-521
Hydrocodone/APAP	10/650	-297
Hydrocodone/APAP	5/500	-819
Hydrocodone/APAP	7.5/325	-846
Alprazolam	0.25	-1189
Alprazolam	.5	-1158
Alprazolam	1	-1046
Phentermine	37.5	-161
Diazepam	10	-51
Hydrocodone/APAP	10/500	-305
Hydrocodone/APAP	7.5/500	-30
Hydrocodone/APAP	7.5/650	-826

- 6. The Pharmacy lost a total of 9,705 units of controlled substances from February 19, 2009 through August 19, 2009 in violation of 20 CSR 2220-2.010(1)(H)(O), 19 CSR 30-1.031(1)(2), 19 CSR 30-1.034(1), 21 CFR 1301.71(a) and 1301.75(b).
- 7. Inspectors Kidd and Wood ("the Inspectors") conducted an inspection of the Pharmacy on 8-19-2009.
- 8. On or about 8-19-2009, the Inspectors observed that the controlled substance purchase records for the Pharmacy were mixed in with regular drug purchase records in violation of 19 CSR 30-1.041(4)A) and 21 CFR 1304.04(H).
- 9. On or about 8-19-2009, the Inspectors observed that the Pharmacy's controlled substance records were not dated on the date received in violation of 30 CSR 19-1.044(4) and 1.048(1)(C) and 21 CFR 1304.22(C) and 1304.21(A)(D).
- 10. In a letter to the Board dated June 29, 2009 from the Pharmacy permit holder, the permit holder reported that the Pharmacy had started a written inventory of the controlled substances in the Pharmacy in order to accurately track controlled substances.
- 11. Based on the June 29, 2009 letter from the Pharmacy, the Board believed and relied on the permit holder's representations that the Pharmacy was maintaining accurate controlled substance records.
- 12. On or about 8-19-2009, the Inspectors observed the following record violations:

a. The inventory control record for the drug Phentermine 37.5 mg was observed to be inaccurate in that it failed to list the date(s) new drug(s) were received, the source of the drug(s), no reason or explanation was documented for corrections made to the record and the running total number of units on hand as well as the ending total for this drug was not accurate. The actual quantity on hand in the Pharmacy on 8-19-2009 was only 165 units, the Pharmacy's inventory record reflected an end total of 191 for a shortage of 26 tablets or 14% unaccounted for.

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- b. On 8-19-2009, the inventory control book for the drug Adipex-P 37.5 mg showed an inventory of 70 tablets minus a dispensing of 23 for a balance of 47 tablets. The inventory book listed the balance as 0. The actual quantity the Pharmacy had in stock on 8-19-2009 was 100 tablets. These tablets were not added to the inventory book.
- 13. The inventory the Pharmacy took on 2-19-2009 was deficient in that:
 - A. The inventory does not have the correct name of the Pharmacy. It states Medi-Care Plus Pharmacy and not Pharmax Pharmacy.
 - B. The inventory does not have the address of the Pharmacy.
 - C. The inventory does not have the DEA number of the Pharmacy.
 - D. The inventory does not list Open or Close to indicate the time the inventory was taken.
 - E. The inventory does not list the controlled substance Suboxone which the Pharmacy had been dispensing according to Pharmacy patient printouts.
- 14. The Pharmacy's inventory records were not accurate and missing information in violation of 19 CSR 30-1.042(1)(D).

- 15. On or about 8-19-2009, the Inspectors observed a repackaged prescription vial of Lisinopril tablets on the Pharmacy's active shelves. The Lisinopril vial had an expiration date in excess of 12 months in violation of 20 CSR 2220-2.120(1)(C)(D) which states:
 - (C) The maximum expiration date allowed for prepacked drugs shall be the manufacturer's expiration date or twelve (12) months, whichever is less; and
 - (D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.
- 16. The Inspectors observed a box of Morphine Sulfate 100 mg. suppositories sitting on the open, active shelves of the Pharmacy. Morphine is a class II drug and is required to be stored in a locked Narcotic Cabinet pursuant to 19 CSR 30-1.034(1)(A).
- 17. The Inspectors observed numerous invoices for controlled substances that were not dated by the person checking the controlled substance order in violation of 30 CSR 19-1.044(4) and 1.048(1)(C) and 21 CFR 1304.22(C) (A)(2)(iv) and 1304.21(A)(D).
- 18. The Pharmacy dispensed prescription RX 4090334 to S.J. for the controlled substance Xanax 0.25 mg with only an electronic signature.
- 19. In March 2008, June 2008 and June 2009, the Inspectors observed overfilled stock bottles in the Pharmacy that were misbranded in violation of section 196.100 and 196.015, RSMo and Title 21 of the U.S. Code, section 331.

- 20. Due to an alleged computer failure, the Pharmacy was missing records in violation of 20 CSR 2220-2.080(2).
- 21. Licensee failed to provide adequate security to detect and prevent drug diversion in violation of 19 CSR 30-1.031(1).
- 22. Licensee failed to maintain accurate controlled substance records in violation of section 195.050.6, RSMo and 19 CSR 30-1.044(1).
- 23. Licensee's failure to properly report the loss of controlled substances constitutes violations of Section 338.100, RSMo, 19 CSR 30-1.034(2)(B), and 21 CFR 1301.76(B).
- 24. Licensee's conduct constitutes a violation of 20 CSR 2200-2.010(1)(N), which states:
 - (N) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.
- 25. The Pharmacy's disregard for state and federal laws subjects the public to an increased risk that controlled substances will not be properly stored, packaged, labeled, and dispensed, thereby posing a danger to the public health and safety.

- 26. Federal and state laws regulating controlled substances exist because controlled substances are dangerous to the public if not properly stored, packaged, labeled, prescribed and dispensed.
- 27. At the time of the events alleged herein, the Pharmacy had formed a relationship of professional trust and confidence with its patients in that its patients relied upon the professional expertise of Holman to ensure that all applicable state and federal laws and regulations regarding the practice of pharmacy were followed.
- 28. The Pharmacy's conduct as alleged herein violated its patients' professional trust and confidence.
- 29. The Pharmacy's conduct as alleged herein constitutes misconduct and gross negligence in the performance of the functions or duties of a licensed pharmacist in violation of section 338.055.2(5), RSMo.
- 30. The Pharmacy's conduct as alleged herein constitutes a violation of professional trust or confidence in violation of section 338.055.2(13), RSMo.
- 31. The Pharmacy's conduct as alleged herein constitutes a violation of the drug laws or rules and regulations of this state and the federal government in violation of section 338.055.2(15), RSMo.
- 32. Cause exists to discipline the Pharmacy's permit for violations of section 338.055.2(5), (6), (13) and (15), RSMo, which states, in relevant part:

- 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
 - (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
 - (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
 - (13) Violation of any professional trust or confidence;
 - (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of § 621.045.3, as amended.

Licensee's permit to operate a pharmacy in the State of Missouri, Permit
No. 004884 is hereby VOLUNTARILY SURRENDERED.

- 2. The parties to this Agreement understand that the Board of Pharmacy will maintain this settlement agreement as an open and public record of the Board as provided in Chapters 324, 338, and 610, RSMo.
- 3. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.
- 4. Licensee, together with its heirs and assigns, and its attorney(s), do hereby waive, release, acquit, and forever discharge the Board, its respective members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to § 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this case, its settlement, or from the negotiation or execution of its settlement. Licensee acknowledges that this paragraph is severable from the remaining portions of this settlement agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

- 5. Licensee understands that it may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Licensee's license. If Licensee desires the Administrative Hearing Commission to review this Agreement, Licensee may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.
- 6. If Licensee requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Licensee's license. If Licensee does not request review by the Administrative Hearing Commission, the settlement agreement goes in to effect 15 days after the document is signed by the Executive Director of the Board.

LICENSEE

TITLE:

Pharmax Pharmacy

Date March 18, 2011

BOAR

KIMBERLY GRINSTON, J.D.

Executive Director

Missouri Board of Pharmacy

Date 5 - 2 - 1/

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